K001392

AUG 21 2000

510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact	Owner/ Operator Provalis Diagnostics Limited Newtech Square Deeside Industrial Park Deeside Flintshire CH5 2NT UK
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Company	Devices and Diagnostics Consulting Group
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Date Prepared	19th April 2000

2) Device name	Proprietary name: Common name: Classification:	Glycosal™ HbA_{1c} Test Laboratory test for the detection of Glycated Haemoglobin in Human Whole Blood. ASSAY, GLYCOSYLATED HAEMOGLOBIN
3) Predicate Device	The Glycosal™ HbA_{1c} test is substantially equivalent to other products in commercial distribution for similar use, including Isolab Inc. Glyc-Affin™ Glycohemaglobin assay, which is currently distributed in the USA by Sigma Chemicals (primary predicate device).	
4) Device Description	Instrument read, single use *in vitro* test for the quantitative determination of glycated haemoglobin (GHb) in diabetics.	
5) Intended use	The Glycosal™ assay is an affinity chromatography method and is intended for the in-vitro quantitative determination of A_{1c} (HbA_{1c}) in capillary blood taken from a finger prick or whole blood in Heparin or EDTA. The test is indicated for monitoring the time averaged blood glucose levels of known diabetics as an indicator of overall glycaemic control. The Glycosal™ assay is intended for use in a physicians/doctors office. The assay it is not intended as a home use test or for self-testing.	

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New Device vs Predicate Device,

Feature	Candidate Device Glycosal™ HbA_{1c} test	Primary Predicate Device Isolab Inc. Glyc-Affin™ Glycohaemoglobin Assay	Differences
Intended use	The Glycosal™ assay is intended for the in-vitro quantitative determination of A_{1c} (HbA_{1c}) in capillary blood taken from a finger prick or whole blood in Heparin or EDTA. The purpose of this test is to monitor the time averaged blood glucose levels of known diabetics as an indicator of overall glycaemic control. The test is to be carried out as a physicians/doctors office assay it is not intended as a home use test or for self testing.	The Total Glycated Hemoglobin (GHb) Kit is intended for the quantitative determination of glycated hemoglobins in whole blood at 415nm.	Identical except Glycosal™ test can use both capillary and whole blood
Detects	Glycated Haemoglobin (GHb)	Glycosylated Hemoglobins (GHb)	Identical
Methodology	Rapid Affinity Chromatography test	Affinity Chromatography test	Identical
Does the device perform a diagnostic interpretation?	No	No	Identical
Quantitative test?	Yes (reader interpreted)	Yes (Spectrophotometer interpreted)	Identical but reader supplied with Glycosal™ test
Device (system) components	Glycosal™ Assay test cartridge (a micro-column within a rotating housing, integrating with optical fraction collection chambers) and	Hemolyzing reagent, GHb columns, column preparation buffer, wash buffer, elution buffer.	Differences; Glycosal™ test supplied as a self contained unit

	hand-held spectrophotometer (HaemaQuant™)		
Minimum test sample	10µl whole blood per test	50µl hemolysate	Differences; Glycosal™ test no sample preparation required
Procedural steps	1. Add sample 2. Incubate sample for 60 seconds. 3. Pour sample 4. Wash 5. Elute fraction 6. Read result	1. Prepare hemolysate 2. Add sample to column 3. Rinse sample into column 4. Incubate for 10 minutes. 5. Wash column. 6. Elute fraction. 7. Read result	Differences; Glycosal™ test has 6 steps as opposed to 7. No sample preparation required.
Total test time	4 minutes	30 minutes	Differences; Glycosal™ test has a shorter test time.
Quality control	Several parameters are controllable: Assay controls are separately available Batch identification system Instrument Quality Control Device Internal procedural control provided by the instrument	Assay controls are separately available. Batch identification system	Differences; use of machine error codes
Storage recommendation	Room temperature	Room temperature	Identical

6) Performance Characteristics

Clinical Studies

Clinical trial carried out at Wrexham Maelor hospital to evaluate a rapid blood test for the measurement of Glycated protein in subjects with type I and type II diabetes mellitus

The data from in excess of 93 patients demonstrated that the Glycosal assay is substantially equivalent to the Isolab Total Glycated Haemoglobin assay with a correlation coefficient of 0.96 for both fresh finger prick and stored EDTA blood.

POL Studies

Evaluation of the Glycosal™ HbA_{1c} test using non-laboratory participants
4 separate Physician Office Laboratory (POL) studies were carried out. Each consisting of 5 standards run in triplicate and at least 20 blood samples (EDTA stored blood and or fresh finger prick) run by a trained operator and an un-trained operator. Each site produced acceptable data for accuracy and precision, with correlation coefficients of ≥ 0.92, accuracy within $\pm$ 10% and CV less than 5%.

Non Clinical Laboratory Studies

Assessing the linearity of the Glycosal™ assay
A study was conducted to prove the Glycosal™ assay is linear over the assay range. Results demonstrated that the assay is linear between 4.35 and 14.9% HbA_{1c}.

The effect of Haemoglobinopathies on the Glycosal™ assay
This validation is covered by reference WG John. Glycated haemoglobin analysis. Ann Clin Biochem 1997; 34: 17-31. Boronate methodology is not affected by HbS, HbC, HbF or by high levels of carbamylated haemoglobin in Uremic patients.

The Effect of Abnormal blood chemistries upon the accuracy of the Glycosal™ Test
The effect of abnormal blood chemistries, *i.e.* raised bilirubin and lipids upon the determination of $\%HbA_{1c}$ needed to be investigated. Bilirubin up to 145 µmol/L and triglycerides up to 8.6 mmol/L do not affect the test result.

The Effect of Interfering Drugs upon Accuracy of the Glycosal™ test
The effect of the commonly prescribed pharmaceutical drugs (aspirin, paracetemol, caffeine and anti-histamine) upon the performance of the *Glycosal™* HbA_{1c} test needed to be assessed. None of the listed compounds affected the HbA_{1c} test result.

Investigating the effect of labile HbA_{1c} on the Glycosal™ assay
This validation is covered by reference WG John. Glycated haemoglobin analysis. Ann Clin Biochem 1997; 34: 17-31. Boronate Methodology is not affected by Labile HbA_{1c}.

Investigating the analysis of variance of reproducibility of the Glycosal™ assay
A study was performed to investigate the analysis of variance of reproducibility of the Glycosal™ assay. Using a normal and an abnormal control, which were assayed in duplicate twice during each day over a period of 20 days, it was demonstrated that the variance was acceptable, with an overall CV precision of less than 5%.

Investigating the assay reproducibility (Inter batch variation) of the Glycosal™ assay
A study was performed to determine the intra and inter batch variation of the Glycosal™ assay. Using a normal and abnormal control sample on 3 batches of Glycosal™ devices it was demonstrated that the Glycosal™ assay was acceptable in terms of repeatability and reproducibility with assay %CV's of less than 5%.

The effect of temperature on the performance of the Glycosal™ assay
The effect of working temperature on the Glycosal™ assay needed to be established. Results demonstrated that the assay performs acceptably between 17 and 30°C.

Investigation into the use of stored blood for the Glycosal™ assay
The effect of running Glycosal™ assays with stored whole blood (Heparin and EDTA) needed to be examined to assess the use of stored whole blood as an alternative to fresh finger pricks. It was demonstrated that the assay can be run acceptably with fresh finger prick, EDTA and heparinised blood for up to 4 days after collection when the blood is stored at 2-8°C.

Investigating the effect of Total Haemoglobin and Haematocrit on the Glycosal™ assay
The effect of the variation in total haemoglobin and haematocrit on $\%HbA_{1c}$ needed to be established. Results demonstrated that the assay pefroms acceptably within a haemoglobin range of 8-20g/dl and a haematocrit range of 30% to 60%.

Glycosal™ test cartridge stability
The stability of the Glycosal™ assay needed to be established. Results demonstrated that the assay is stable for at least 7 months at 25°C

Glycosal™ Quality Control Kit
Provalis use commercially available controls from Aalto scientific Ltd; Glycohemoglobin controls normal and abnormal. 510(k) K952720.

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7) Conclusion: These performance characteristics clearly indicate substantial equivalence with the Isolab Inc. Glyc-Affin™ Glycohemaglobin assay and provides a comparative accuracy to other cleared and commonly accepted methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 21 2000

Provalis Diagnostics Limited
c/o Tom Tsakeris
Devices & Diagnostics Consulting Group
16809 Briardale Road
Rockville, Maryland 20855

Re: K001392
Trade Name: Provalis Glycosal HbA_{1C} Test
Regulatory Class: II
Product Code: LCP
Dated: July 11, 2000
Received: July 11, 2000

Dear Mr. Tsakeris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Intended use/Indications for Use Statement

510(k) Number: *Unknown-not yet assigned by FDA* K001392

Device Name: Glycosal™ HbA_{1c} Test

Intended use/Indications for use statement:

The Glycosal™ HbA_{1c} assay is an affinity chromatography method and is intended for the in-vitro quantitative determination of A_{1c} (HbA_{1c}) in capillary blood taken from a finger prick or whole blood in Heparin or EDTA.

The test is indicated for monitoring the time averaged blood glucose levels of known diabetics as an indicator of overall glycaemic control.

The Glycosal™ HbA_{1c} assay is intended for use in a physicians/doctors office. The assay it is not intended as a home use test or for self-testing.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean E Mahieu

(Division Sign-Off)
Division of Clinical Laboratory Devices K001392
510(k) Number

✓
Prescription Use (Per 21CFR801.109) OR Over-The-Counter Use